

## VIII. SAFETY AND EFFECTIVENESS SUMMARY

The STA®-Liatest® Free Protein S kit is intended for use on various models of the STA® family of analyzers (STA®, K942117; STA Compact®, K961579; STA-R®, K983460) for the quantitative determination of the free Protein S antigen level in citrated plasma by the immuno-turbidimetric method based on the change in turbidity of a suspension of microparticles coated with two different mouse monoclonal antibodies specific for free Protein S.

Each kit provides 2 reagents: Reagent [1] is a HEPES buffer; Reagent [2] is a suspension of microlatex particles coated with two different mouse monoclonal anti-human free Protein S antibodies. The kit reagents are precalibrated for each manufactured lot.

Intact vials in unopened kits have a shelf-life is 18 months after the date of manufacture, when stored at 2°-8°C. After vial opening the reagents remain stable for 5 days on board STA® analyzers.

The STA®-Liatest® Free Protein S reagent system has a detection limit of 8% free Protein S and a working range of 8%-150% free Protein S.

The STA®-Liatest® Free Protein S kit is substantially equivalent to the predicate device ASSERACHROM® Free Protein S (Diagnostica Stago, France; K954017) which is an enzyme-linked immunosorbent assay (ELISA) for free Protein S using antibody-coated micro-ELISA plates.



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN - 6 2001

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Andrew Loc B. Le, Ph.D.  
Director for Regulatory Affairs and Quality Assurance  
Diagnostica Stago, Inc.  
Five Century Drive  
Parsippany, New Jersey 07054

Re: K010963  
Trade Name: Diagnostica Stago STA®-Liatest® Free Protein S Kit  
Regulation Number: 21 CFR 864.7290  
Regulatory Class: II  
Product Code: GGP  
Dated: March 30, 2001  
Received: March 30, 2001

Dear Dr. Le:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

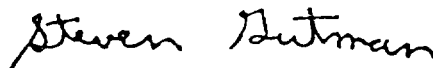
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Attachment A**


Page 1 of 1

510(k) Number: K010963

Device Name: STA®-Liatest® Free Protein S Test Kit

Indications for Use:

The STA®-Liatest® Free Protein S test kit is intended for use on various models of the STA® analyzers for the quantitative determination of the free Protein S level in citrated plasma by the immuno-turbidimetric method.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K010963

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)